April 11, 2003

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INTELLECTUAL PROPERTY LAW

VIA FACSIMILE - CONFIRMED BY MAIL

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Mr. David Grosky
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Chief Scientific Officer
Prion Developmental Laboratories, Inc.
900 Asbury Drive
Buffalo Grove, Illinois 60089

Re: U.S. Patent Application for "Prion-Detection Business Methods"
Application No.: 09/990,773 -- Filed: November 14, 2001
Our File No. 4110 P 004

Dear David and Kiam:

Enclosed is the first Office Action on the merits in the above-identified Application. Also attached is a copy of the pending Claims.

In this Action, the Examiner (Dr. Rodney Swartz) rejected all of the Claims as being "non-enabling." (Section 112). Under the U.S. patent laws, a patent must disclose sufficient information to enable those skilled in the art (a person of ordinary skill in the art) to make and use the claimed invention. This requirement is known as the enablement requirement. 35 U.S.C. § 112. A patent need not disclose what is well known in the art.

This is, in all likelihood, a result of the wording of the Claims and the Examiner's interpretation thereof.

In particular, in Paragraph 6, the Examiner rejects Claims 1 and 3-13 because he believes - while the specification discloses an enabling method for detecting prion disease utilizing antibodies specific for PrP(SC) - it does not provide an enabling disclosure for detecting "all" other diseases in animal carcasses. The Claims' preamble call for "A method for detecting disease in animal carcasses." Our initial hunch is that the Examiner wants us to limit the Claims to detection of prion diseases, such as those set forth in Claims 2 and 14-34.

Similarly, in Paragraph 7, the Examiner rejects Claims 1-34 because the Examiner believes - while the specification discloses an enabling method for detecting prion disease utilizing antibodies specific for PrP(SC) - it does not provide an enabling disclosure for distinguishing between diseased and nondiseased carcasses by detecting merely prion protein using antibodies other than those specific for PrP(SC). The Examiner appears to be saying that the detection of prion is only a factor

for consideration and not a diagnosis. In short, the detection of prion (PrP(SC)) is not an absolute indicator of the diseased animal.

The Examiner further notes that the prior art for prion disease detection is improving with new specific antibodies and assays. "However, the predictability in the art of prion disease diagnosis highly depends on the specificity of the antibodies to the disease conformation of PrP." The Examiner further notes that the specification shows no actual working examples of the inventions, only parameters of sample handling and procedures which "applicants indicate should result in the claimed invention."

As a starting point, some or all of above may be overcome by narrowing the scope of the Claims to "A method for detecting prion disease utilizing antibodies specific for PrP(SC)." The other objections and rejections appear to be to form and we should be able to merely clean them up.

It also appears that the Examiner has not yet conducted an independent search of the art. That will probably occur after the above has been rectified.

A response to this Office Action is due **June 26, 2003**. This can be extended to July 26, 2003 with payment of a $55 fee; to August 26, 2003 with payment of a $205 fee; and to September 26, 2003 with payment of a $465 fee.

We ask you to carefully review the Action and advise/instruct us as to how you would like us to proceed. Please call if you have any questions.

Very truly yours,

Roger

Roger H. Stein

Kmr

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Enclosures

ATTACHMENT

ENABLEMENT

Under the U.S. patent laws, a patent must disclose sufficient information to enable those skilled in the art (a person of ordinary skill in the art) to make and use the claimed invention. This requirement is known as the enablement requirement. 35 USC§112. A patent need not disclose what is well known in the art.

A patent is enabling even if some experimentation would be required to achieve the claimed invention, so long as that amount of experimentation is routine and would not be considered undue by those skilled in the art. Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims.